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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BIOGEN IDEC MA INC., Plaintiff, v. EMD SERONO, INC.; PFIZER INC.; BAYER HEALTHCARE PHARMACEUTICALS INC.; and NOVARTIS PHARMACEUTICALS CORP., Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR TRIAL BY JURY**

Plaintiff Biogen Idec MA Inc. ("Biogen") for its Complaint against Defendants EMD Serono, Inc. ("Serono"); Pfizer Inc. ("Pfizer"); Bayer Healthcare Pharmaceuticals Inc. ("Bayer"); and Novartis Pharmaceuticals Corp. ("Novartis") alleges as follows:

THE PARTIES

1. Biogen is a corporation organized and existing under the laws of the Commonwealth of Massachusetts with its principal place of business at 14 Cambridge Center, Cambridge, Massachusetts 02142. Biogen is a leading biotechnology company in the United States focusing on various therapeutic products, including, but not limited to, immunomodulators. Biogen's products have earned wide acceptance by both physicians and

patients, including, but not limited to, Biogen's AVONEX®, an interferon-beta ("IFN-β") product that is approved by the U.S. Food and Drug Administration ("FDA") for the treatment of relapsing forms of multiple sclerosis to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations via immunomodulation.

2. On information and belief, Defendant Serono is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at One Technology Place, Rockland, Massachusetts 02370. On information and belief, Serono is in the business of manufacturing various therapeutic products, including, but not limited to, REBIF®, an IFN-β product that is FDA-approved for the treatment of multiple sclerosis via immunomodulation, and distributing and/or selling those products in the State of New Jersey and throughout the United States.

3. On information and belief, Defendant Pfizer is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 235 East 42nd Street, New York, New York 10017. On information and belief, Pfizer is in the business of marketing various therapeutic products, including, but not limited to, REBIF®, an IFN-β product that is FDA-approved for the treatment of multiple sclerosis via immunomodulation, and distributing and/or selling those products in the State of New Jersey and throughout the United States.

4. On information and belief, Defendant Bayer, formerly known as Berlex Inc. ("Berlex"), is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 340 Changebridge Road, Montville, New Jersey 07045. On information and belief, Bayer is in the business of manufacturing various therapeutic products, including, but not limited to, BETASERON® and EXTAVIA®, IFN-β products that are FDA-

approved for the treatment of multiple sclerosis via immunomodulation, and distributing and/or selling those products in the State of New Jersey and throughout the United States.

5. On information and belief, Defendant Novartis is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Health Plaza, East Hanover, New Jersey 07936. On information and belief, Novartis is in the business of marketing various therapeutic products, including EXTAVIA®, an IFN-β product that is FDA-approved for the treatment of multiple sclerosis via immunomodulation, and distributing and/or selling those products in the State of New Jersey and throughout the United States.

NATURE OF THE ACTION

6. This is an action arising under the patent laws of the United States (Title 35, United States Code, § 100, *et seq.*) based upon Serono and Pfizer's infringement of one or more of claims 1-3 and Bayer and Novartis's infringement of claim 1 of Biogen's U.S. Patent No. 7,588,755, entitled "DNA SEQUENCES, RECOMBINANT DNA MOLECULES AND PROCESSES FOR PRODUCING HUMAN FIBROBLAST INTERFERON-LIKE POLYPEPTIDES" ("the '755 patent"), relating generally to immunomodulation and treatments using recombinant interferon-like polypeptides, including IFN-β.

7. Serono filed Biologics License Application No. 103780 (the "Serono BLA") under § 351(a) of the Public Health Service Act (the "PHSA"), 42 U.S.C. § 262(a), to obtain approval to commercially make, use, offer to sell, and/or sell IFN-β for the treatment of multiple sclerosis via immunomodulation. The FDA approved the Serono BLA on March 7, 2002, and Serono began to market its IFN-β product under the trade name REBIF®.

8. Serono currently is making, using, offering to sell and/or selling REBIF® in the United States for the treatment of multiple sclerosis via immunomodulation.

9. On information and belief, in 2002, Pfizer entered into an agreement with Serono to co-promote REBIF®. On May 2, 2003, the FDA approved a change to the REBIF® package insert to reflect the fact that REBIF® is co-marketed by Serono and Pfizer.

10. Pfizer currently is using, offering to sell and/or selling REBIF® in the United States for the treatment of multiple sclerosis via immunomodulation.

11. Chiron Corp. ("Chiron") and Berlex (now Bayer) filed Biologics License Application No. 103471 (the "Bayer BLA") under § 351(a) of the PHSA, 42 U.S.C. § 262(a), to obtain approval to commercially make, use, offer to sell, and/or sell IFN-β for the treatment of multiple sclerosis via immunomodulation. The FDA approved the Bayer BLA on July 23, 1993, and Chiron began to manufacture and Berlex (now Bayer) began to distribute their IFN-β product under the trade name BETASERON®.

12. On information and belief, in 2006, Novartis acquired Chiron, including rights to the Bayer BLA. In an agreement between Novartis and Bayer in 2007, Bayer became the exclusive license holder of the Bayer BLA and Bayer agreed to manufacture BETASERON® for Novartis as a separate brand under a separate BLA.

13. Bayer currently is making, using, offering to sell and/or selling BETASERON® in the United States for the treatment of multiple sclerosis via immunomodulation.

14. On May 6, 2008, Novartis and Bayer filed Biologics License Application No. 125290 (the "Novartis BLA") under § 351(a) of the PHSA, 42 U.S.C. § 262(a), to obtain approval to commercially make, use, offer to sell, and/or sell IFN-β for the treatment of multiple sclerosis via immunomodulation. The FDA approved the Novartis BLA on August 14, 2009,

and Bayer began to manufacture and Novartis began to distribute their IFN-β product under the trade name EXTAVIA®.

15. Bayer currently is making, using, offering to sell and/or selling EXTAVIA® in the United States for the treatment of multiple sclerosis via immunomodulation.

16. Novartis currently is using, offering to sell and/or selling EXTAVIA® in the United States for the treatment of multiple sclerosis via immunomodulation.

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction over Biogen's patent infringement claims under 28 U.S.C. §§ 1331 and 1338(a).

18. This Court has personal jurisdiction over Serono, by virtue of, inter alia, it having conducted business in New Jersey, having availed themselves of the rights and benefits of New Jersey law, and having engaged in substantial and continuing contacts with the State.

19. On information and belief, Serono conducts substantial business in this judicial district, regularly solicits business from, does business with, and derives value from goods and services provided to customers in this judicial district, employs individuals and conducts clinical trials in this judicial district, and have committed acts of infringement in this judicial district, including selling and offering to sell REBIF®, and such acts are and will be continuing.

20. Serono has previously submitted to the jurisdiction of this Court for purposes of litigating its patent dispute. In 1997, Serono, then operating as Serono Laboratories, Inc., litigated a patent infringement lawsuit styled Novo Nordisk of N.A. v. Genentech, Inc., C.A. No. 3:97-cv-04848-AET (D.N.J.).

21. This Court has personal jurisdiction over Pfizer, by virtue of, inter alia, it having conducted business in New Jersey, having availed themselves of the rights and benefits of New Jersey law, and having engaged in substantial and continuing contacts with the State.

22. On information and belief, Pfizer conducts substantial business in this judicial district, has offices and manufacturing facilities in this judicial district, regularly solicits business from, does business with, and derives value from goods and services provided to customers in this judicial district, and have committed acts of infringement in this judicial district, including selling and offering to sell REBIF®, and such acts are and will be continuing.

23. Pfizer has previously availed itself of this forum for purposes of litigating its patent dispute. For example, in 2007, Pfizer filed a patent infringement lawsuit styled Pfizer Inc. v. Ivax Pharmaceuticals, Inc., Civil Action No. 07-174-DMC-MF (D.N.J.). Pfizer also has submitted to the jurisdiction of this Court and asserted counterclaims in other civil actions initiated in this jurisdiction, including, but not limited to Armkel, LLC v. Pfizer Inc., Civil Action No. 02-4206 (D.N.J.); and Inverness Medical SW v. Pfizer Inc., Civil Action No. 02-1029-KSH-PS (D.N.J.).

24. This Court has personal jurisdiction over Bayer, by virtue of, inter alia, it residing in this judicial district, having conducted business in New Jersey, having availed themselves of the rights and benefits of New Jersey law, and having engaged in substantial and continuing contacts with the State. In addition, on May 27, 2010, Bayer filed an action against Biogen Idec Inc. (Biogen's parent corporation) on the same patent, the '755 patent, in this Court.

25. This Court has personal jurisdiction over Novartis, by virtue of, inter alia, it residing in this judicial district, having conducted business in New Jersey, having availed

themselves of the rights and benefits of New Jersey law, and having engaged in substantial and continuing contacts with the State.

26. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 (b) and (c) and 1400(b) because, on information and belief, Bayer and Novartis are headquartered in this judicial district and Defendants have committed and are continuing to commit acts of infringement in this judicial district, provide a substantial volume of goods and do a substantial amount of business within this judicial district, employ individuals and conduct clinical trials in this judicial district, and thus purposefully avail themselves of the privilege of conduction activities within New Jersey.

THE PATENT-IN-SUIT
(U.S. PATENT NO. 5,908,755)

27. The allegations of ¶¶ 1-26 are incorporated herein by reference.

28. Biogen is the owner of all right, title and interest in the ’755 patent. The United States Patent and Trademark Office duly and legally issued the ’755 patent on September 15, 2009, to Walter Charles Fiers, which was assigned to Biogen. A true and correct copy of the ’755 patent is attached to this Complaint as Exhibit A.

29. Defendants state in their respective package inserts and/or labels for REBIF®, BETASERON®, and EXTAVIA® that the products are IFN-β products that are approved for the treatment of multiple sclerosis.

30. The use of REBIF®, BETASERON®, and EXTAVIA® for the treatment of multiple sclerosis via immunomodulation is covered by the ’755 patent, and Biogen has the right to enforce the ’755 patent.

31. On information and belief, Defendants were aware of the existence of the '755 patent prior to the filing of this complaint. Defendants, however, do not have a license to the '755 patent.

FIRST COUNT FOR RELIEF
(INFRINGEMENT OF THE '755 PATENT BY DEFENDANT SERONO)

32. The allegations of ¶¶ 1-31 are incorporated herein by reference.

33. On information and belief, Serono obtained FDA approval to commercially manufacture, use, offer for sale and sell REBIF® for the treatment of multiple sclerosis via immunomodulation under the Serono BLA before the expiration of the '755 patent.

34. On information and belief, in 2002 Serono and Pfizer supplemented the Serono BLA and obtained approval to co-market REBIF® for the treatment of multiple sclerosis via immunomodulation before the expiration of the '755 patent.

35. On information and belief, Serono has commercially manufactured, used, offered for sale and sold REBIF® for the treatment of multiple sclerosis via immunomodulation before the expiration of the '755 patent.

36. Serono has infringed the '755 patent under 35 U.S.C. § 271(a), (b) and (c) by virtue of its commercial manufacture, use, offer for sale and sale of REBIF® in the United States for the treatment of multiple sclerosis via immunomodulation that are covered by one or more of claims 1-3 of the '755 patent.

37. Serono was aware of the existence of the '755 patent prior to the filing of this complaint, but has refused to take a license to the '755 patent. Serono continues to manufacture, sell and offer to sell REBIF® in willful, intentional, and deliberate infringement of one or more of claims 1-3 of the '755 patent.

38. Serono and Pfizer are jointly and severally liable for any infringement of one or more of claims 1-3 of the '755 patent. Serono and Pfizer's participation in, contribution to, aiding, abetting, and/or inducement of the use of REBIF® for the treatment of multiple sclerosis via immunomodulation constitutes infringement of one or more of claims 1-3 of the '755 patent under 35 U.S.C. § 271(a), (b) and (c).

39. Biogen will be irreparably harmed by Serono if Serono continues to infringe, actively induce infringement or contribute to the infringement of one or more of claims 1-3 of the '755 patent. Biogen does not have an adequate remedy at law.

40. Biogen is also entitled to damages under 35 U.S.C. § 284 for Serono's infringement and willful infringement of one or more of claims 1-3 of the '755 patent.

SECOND COUNT FOR RELIEF
(INFRINGEMENT OF THE '755 PATENT BY DEFENDANT PFIZER)

41. The allegations of ¶¶ 1-40 are incorporated herein by reference.

42. On information and belief, Serono obtained FDA approval to commercially manufacture, use, offer for sale and sell REBIF® for the treatment of multiple sclerosis via immunomodulation under the Serono BLA before the expiration of the '755 patent.

43. On information and belief, in 2002 Serono and Pfizer supplemented the Serono BLA and obtained approval to co-market REBIF® for the treatment of multiple sclerosis via immunomodulation before the expiration of the '755 patent.

44. On information and belief, Serono has commercially manufactured and Serono and Pfizer have used, offered for sale and sold REBIF® for the treatment of multiple sclerosis via immunomodulation before the expiration of the '755 patent.

45. Pfizer has infringed the '755 patent under 35 U.S.C. § 271(a), (b) and (c) by virtue of its use, offer for sale and sale of REBIF® in the United States for the treatment of

multiple sclerosis via immunomodulation that are covered by one or more of claims 1-3 of the '755 patent.

46. Pfizer was aware of the existence of the '755 patent prior to the filing of this complaint, but has refused to take a license to the '755 patent. Pfizer continues to sell and offer to sell REBIF® in willful, intentional, and deliberate infringement of one or more of claims 1-3 of the '755 patent.

47. Serono and Pfizer are jointly and severally liable for any infringement of one or more of claims 1-3 of the '755 patent. Serono and Pfizer's participation in, contribution to, aiding, abetting, and/or inducement of the use of REBIF® for the treatment of multiple sclerosis via immunomodulation constitutes infringement of one or more of claims 1-3 of the '755 patent under 35 U.S.C. § 271(a), (b) and (c).

48. Biogen will be irreparably harmed by Pfizer if Pfizer continues to infringe, actively induce infringement or contribute to the infringement of one or more of claims 1-3 of the '755 patent. Biogen does not have an adequate remedy at law.

49. Biogen is also entitled to damages under 35 U.S.C. § 284 for Pfizer's infringement and willful infringement of one or more of claims 1-3 of the '755 patent.

THIRD COUNT FOR RELIEF
(INFRINGEMENT OF THE '755 PATENT BY DEFENDANT BAYER)

50. The allegations of ¶¶ 1-49 are incorporated herein by reference.

51. On information and belief, Chiron and Bayer obtained FDA approval to commercially manufacture, use, offer for sale and sell BETASERON® for the treatment of multiple sclerosis via immunomodulation under the Bayer BLA before the expiration of the '755 patent.

52. On information and belief, in 2007 Bayer became the exclusive license holder of the Bayer BLA and has commercially manufactured, used, offered for sale and sold BETASERON® for the treatment of multiple sclerosis via immunomodulation before the expiration of the '755 patent.

53. Bayer has infringed the '755 patent under 35 U.S.C. § 271(a), (b) and (c) by virtue of its commercial manufacture, use, offer for sale and sale of BETASERON® in the United States for the treatment of multiple sclerosis via immunomodulation that are covered by claim 1 of the '755 patent.

54. Bayer was aware of the existence of the '755 patent prior to the filing of this complaint, but has refused to take a license to the '755 patent. Bayer continues to manufacture, sell and offer to sell BETASERON® in willful, intentional, and deliberate infringement of claim 1 of the '755 patent.

55. Bayer's participation in, contribution to, aiding, abetting, and/or inducement of the use of BETASERON® for the treatment of multiple sclerosis via immunomodulation constitutes infringement of claim 1 of the '755 patent under 35 U.S.C. § 271(a), (b) and (c).

56. Biogen will be irreparably harmed by Bayer if Bayer continues to infringe, actively induce infringement or contribute to the infringement of claim 1 of the '755 patent. Biogen does not have an adequate remedy at law.

57. Biogen is also entitled to damages under 35 U.S.C. § 284 for Bayer's infringement and willful infringement of claim 1 of the '755 patent.

FOURTH COUNT FOR RELIEF
(INFRINGEMENT OF THE '755 PATENT BY DEFENDANT BAYER)

58. The allegations of ¶¶ 1-57 are incorporated herein by reference.

59. On information and belief, Novartis and Bayer obtained approval to commercially manufacture, use, offer for sale and sell EXTAVIA® for the treatment of multiple sclerosis via immunomodulation under the Novartis BLA before the expiration of the '755 patent.

60. On information and belief, Bayer has commercially manufactured, used, offered for sale and sold EXTAVIA® for the treatment of multiple sclerosis via immunomodulation before the expiration of the '755 patent.

61. Bayer has infringed the '755 patent under 35 U.S.C. § 271(a), (b) and (c) by virtue of its commercial manufacture, use, offer for sale and sale of EXTAVIA® in the United States for the treatment of multiple sclerosis via immunomodulation that are covered by claim 1 of the '755 patent.

62. Bayer was aware of the existence of the '755 patent prior to the filing of this complaint, but has refused to take a license to the '755 patent. Bayer continues to manufacture, sell and offer to sell EXTAVIA® in willful, intentional, and deliberate infringement of claim 1 of the '755 patent.

63. Bayer and Novartis are jointly and severally liable for any infringement of claim 1 of the '755 patent. Bayer and Novartis's participation in, contribution to, aiding, abetting, and/or inducement of the use of EXTAVIA® for the treatment of multiple sclerosis via immunomodulation constitutes infringement of claim 1 of the '755 patent under 35 U.S.C. § 271(a), (b) and (c).

64. Biogen will be irreparably harmed by Bayer if Bayer continues to infringe, actively induce infringement or contribute to the infringement of claim 1 of the '755 patent. Biogen does not have an adequate remedy at law.

65. Biogen is also entitled to damages under 35 U.S.C. § 284 for Bayer's infringement and willful infringement of claim 1 of the '755 patent.

FIFTH COUNT FOR RELIEF
(INFRINGEMENT OF THE '755 PATENT BY DEFENDANT NOVARTIS)

66. The allegations of ¶¶ 1-65 are incorporated herein by reference.

67. On information and belief, Novartis and Bayer obtained approval to commercially manufacture, use, offer for sale and sell EXTAVIA® for the treatment of multiple sclerosis via immunomodulation under the Novartis BLA before the expiration of the '755 patent.

68. On information and belief, Bayer has commercially manufactured and Bayer and Novartis have used, offered for sale and sold REBIF® for the treatment of multiple sclerosis via immunomodulation before the expiration of the '755 patent.

69. Novartis has infringed the '755 patent under 35 U.S.C. § 271(a), (b) and (c) by virtue of its use, offer for sale and sale of EXTAVIA® in the United States for the treatment of multiple sclerosis via immunomodulation that are covered by claim 1 of the '755 patent.

70. Novartis was aware of the existence of the '755 patent prior to the filing of this complaint, but has refused to take a license to the '755 patent. Novartis continues to sell and offer to sell EXTAVIA® in willful, intentional, and deliberate infringement of claim 1 of the '755 patent.

71. Novartis and Bayer are jointly and severally liable for any infringement of claim 1 of the '755 patent. Novartis and Bayer's participation in, contribution to, aiding, abetting, and/or inducement of the use of EXTAVIA® for the treatment of multiple sclerosis via

immunomodulation constitutes infringement of claim 1 of the '755 patent under 35 U.S.C. § 271(a), (b) and (c).

72. Biogen will be irreparably harmed by Novartis if Novartis continues to infringe, actively induce infringement or contribute to the infringement of claim 1 of the '755 patent. Biogen does not have an adequate remedy at law.

73. Biogen is also entitled to damages under 35 U.S.C. § 284 for Novartis's infringement and willful infringement of claim 1 of the '755 patent.

PRAYER FOR RELIEF

WHEREFORE, Biogen respectfully requests that this Court enter judgment in its favor against Defendants and grant the following relief:

A. an adjudication that Serono has infringed one or more of the following claims of the '755 patent: claims 1-3, under 35 U.S.C. §§ 271(a), (b), and/or (c), by the commercial manufacture, use, offer for sale, or sale in the United States, and/or importation or distribution into the United States, of REBIF® for the treatment of multiple sclerosis via immunomodulation before the expiration of the '755 patent;

B. an adjudication that Pfizer has infringed one or more of the following claims of the '755 patent: claims 1-3, under 35 U.S.C. §§ 271(a), (b), and/or (c), by the use, offer for sale, or sale in the United States, and/or importation or distribution into the United States, of REBIF® for the treatment of multiple sclerosis via immunomodulation before the expiration of the '755 patent;

C. an adjudication that Bayer has infringed claim 1 of the '755 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), by the commercial manufacture, use, offer for sale, or sale in the United States, and/or importation or distribution into the United States, of BETASERON®

for the treatment of multiple sclerosis via immunomodulation before the expiration of the '755 patent;

D. an adjudication that Bayer has infringed claim 1 of the '755 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), by the commercial manufacture, use, offer for sale, or sale in the United States, and/or importation or distribution into the United States, of EXTAVIA® for the treatment of multiple sclerosis via immunomodulation before the expiration of the '755 patent;

E. an adjudication that Novartis has infringed claim 1 of the '755 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), by the use, offer for sale, or sale in the United States, and/or importation or distribution into the United States, of EXTAVIA® for the treatment of multiple sclerosis via immunomodulation before the expiration of the '755 patent;

F. a judgment declaring that the commercial manufacture, use, offer for sale, or sale in the United States, and/or importation or distribution into the United States, of the products described in the Serono BLA, or inducing or contributing to such conduct, would constitute infringement of one or more of claims 1-3 of the '755 patent by Serono and Pfizer pursuant to 35 U.S.C. § 271 (a), (b) and/or (c);

G. a judgment declaring that the commercial manufacture, use, offer for sale, or sale in the United States, and/or importation or distribution into the United States, of the products described the Bayer BLA, or inducing or contributing to such conduct, would constitute infringement of claim 1 of the '755 patent by Bayer pursuant to 35 U.S.C. § 271 (a), (b) and/or (c);

H. a judgment declaring that the commercial manufacture, use, offer for sale, or sale in the United States, and/or importation or distribution into the United States, of the

products described in the Novartis BLA, or inducing or contributing to such conduct, would constitute infringement of claim 1 of the '755 patent by Novartis and Bayer pursuant to 35 U.S.C. § 271 (a), (b) and/or (c);

I. a determination that Defendants' infringement is and has been willful, and that this is an exceptional case under 35 U.S.C. § 285;

J. an award of damages sustained as a result of Defendants' infringement, in an amount to be ascertained at trial, including (i) a reasonable royalty on sales of Defendants' respective products under their respective BLAs; and (ii) Biogen's lost profits;

K. a trebling for any and all damages pursuant to 35 U.S.C. § 284;

L. an assessment of pre-judgment and post-judgment interest and costs against Defendants, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

M. an award of reasonable attorneys' fees, pursuant to 35 U.S.C. § 285; and

N. such other and further relief as this Court may deem just and proper.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Biogen hereby demands a trial by jury on all issues properly so triable.

Dated: May 28, 2010
Chatham, New Jersey

Respectfully submitted,

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